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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,052	07/14/2006	Minami Matsui	P30310	2446
7055 7590 01/13/2009 GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191			EXAMINER WORLEY, CATHY KINGDON	
			ART UNIT 1638	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
pto@gbpatent.com

Office Action Summary	Application No. 10/586,052	Applicant(s) MATSUI ET AL.	
	Examiner CATHY K. WORLEY	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-13 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,10 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,6-9,11 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/17/08; 11/3/08</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed Nov. 3, 2008, has been entered.
2. Claim 5 has been cancelled.
Claim 13 has been newly added is drawn to the elected invention.
Claims 1-4 and 6-13 are pending.
Claims 2, 3, 10, and 12 are withdrawn.
3. Claims 1, 4, 6-9, 11, and 13 are examined in the present office action.
4. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

Information Disclosure Statement

5. The information disclosure statements (IDS) filed July 17, 2008 and Nov. 3, 2008 have been considered. The Examiner lined through the entry under "other documents" on the IDS filed on Nov. 3, 2008, because the indication that only the English Abstract was considered must be included with the entry of the foreign patent (JP 2003-070477). The Examiner added the notation that a translation was provided for the abstract only, and the Examiner initialed this notation.

Objections and Rejections that are Withdrawn

6. The objections to the abstract and the specification for use of the trademark SILWET-L-77 have been withdrawn in light of the Applicant's amendments to the specification and abstract.
7. The objections to claims 1, 7-9, and 11 are withdrawn in light of the Applicant's amendments to the claims.
8. The rejection of claims 1 and 4-6 under 35 USC 101 is withdrawn in light of the Applicant's amendments to the claims.
9. The rejection of claims 1, 4-9, and 11 under 35 USC 112, 2nd paragraph, is withdrawn in light of the Applicant's amendments to the claims.
10. The rejection of claim 9 under 35 U.S.C. 102(b) as being anticipated by Akbergenov et al is withdrawn after further consideration, because Akbergenov et al do not teach the incorporation of the nucleic acids into the genome of the host.
11. All rejections of claim 5 are withdrawn in light of the Applicant's cancellation of claim 5.

Claim Rejections - 35 USC § 112

12. Claims 1, 4, 6-9, 11, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This new rejection was necessitate by the Applicant's amendments to the claims. All dependent claims are included in this rejection.

Claim 1 recites "derived from the nucleotide sequence represented by SEQ ID NO:1 by the substitution, deletion, addition, and insertion of two to five bases"; and it is unclear if this encompasses as many as five substitutions, five deletions, five additions, and five insertions; or if there are only five changes in total. The Examiner will interpret this claim, broadly, to include five substitutions, in addition to five deletions, and in addition to five additions, and in addition to five insertions. This interpretation does not relieve the applicant of addressing this rejection under 35 USC 112, 2nd paragraph.

In addition, claim 13 recites specific substitutions that can be made, however, it is unclear what the positions recited are relative to. The claims limit the substitution, deletion, addition, and insertion to 5 bases, however, SEQ ID NO:1 is only 12 bases in length, therefore, if one were to delete 5 bases and substitute 5 bases; there would only be two of the original bases remaining in a 7-base nucleic acid. Then one can add 5 bases and insert 5 bases, and one would have a 17-base

nucleic acid that has only 2 bases from SEQ ID NO:1 remaining. Once this deletions and insertions and additions are made, it is unclear how the bases would be numbered to make the substitutions being claimed in claim 13.

13. Claims 1, 4, 6-9, and 11 remain and new claim 13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record stated in the previous Office Action mailed on July 1, 2008, and for the reasons stated below. The Applicant's amendments to the claims required modifications to this rejection. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Applicant's arguments in the response filed on Nov. 3, 2008, were fully considered but were not found to be persuasive.

The claims are broadly drawn to a polynucleotide which functions as an IRES in a plant and comprises 7 – 10 repeats of DNA of SEQ ID NO:1 or 7 – 10 repeats of DNA derived from SEQ ID NO:1 by the substitution, deletion, addition, and insertion of two to five bases; and to a vector and plant comprising said polynucleotide. The claims include constructs with repeats of the polynucleotide.

The Applicants describe the nucleic acid of SEQ ID NO:1 which is 12 nucleotides in length (see sequence listing). They describe a construct comprising

10 repeats of SEQ ID NO:1 with spacer sequences between the repeats (see paragraph 0060 on page 17), and they describe a construct comprising 10 repeats of SEQ ID NO:1 without spacer sequences (see first paragraph on page 21). The Applicants describe an IRES from ECMV that is known to function in mammal cells and tobacco (see last paragraph on page 18) and a construct comprising this ECMV IRES (see second paragraph on page 21). The ECMV IRES does not appear to be related to the instant invention of SEQ ID NO:1, and the Applicant has not compared the sequences of the ECMV IRES and the sequence of SEQ ID NO:1. They describe transgenic Arabidopsis plants transformed with these constructs (see page 19); and they describe the effect on expression from using 10 repeats without spacers as "far increased" (see paragraph bridging pages 21-22) and the effect on expression from using 10 repeats with spacers as "slightly increased" (see second paragraph on page 22). They describe the effect on expression from using the ECMV IRES as not increased (see third paragraph on page 22) which demonstrates that an IRES that is active in tobacco and mammalian cells is not active in Arabidopsis.

The Applicants do not describe any DNAs "derived from" SEQ ID NO:1 that function as an IRES. The Applicants do not describe SEQ ID NO:1 as having IRES activity in any plant other than Arabidopsis.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated

that, “A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” See *University of California v. Eli Lilly and Co.*, 119 F. 3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

The Applicants fail to describe a representative number of DNAs “derived from” SEQ ID NO:1 that have IRES activity. The Applicants only describe a construct with 10 repeats of SEQ ID NO:1. Furthermore, the Applicants fail to describe structural features common to members of the claimed genus of SEQ ID NO:1 derivatives. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for IRES function, it remains unclear what features identify SEQ ID NO:1 derivatives capable of such activity. Since the genus of DNAs derived from SEQ ID NO:1 has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

DNAs that are derived from SEQ ID NO:1 by substitution, deletion, addition, and insertion encompass a large number of molecules, many of which would not have IRES activity in a plant, and most of which were not in the possession of the Applicant at the time of filing. The claims limit the substitution, deletion, addition,

and insertion to 5 bases, however, SEQ ID NO:1 is only 12 bases in length, therefore, if one were to delete 5 bases and substitute 5 bases; there would only be two of the original bases remaining in a 7-base nucleic acid. Then one can add 5 bases and insert 5 bases, and one would have a 17-base nucleic acid that has only 2 bases from SEQ ID NO:1 remaining. The Applicants have only reduced to practice in an experiment that demonstrates IRES activity, a polynucleotide comprising 10 repeats of SEQ ID NO:1 which is shown to be active only in Arabidopsis plants. Accordingly, the specification fails to provide an adequate written description to support the genus of DNAs derived from SEQ ID NO:1 that have IRES function or the genus of transformants and transgenic plants comprising SEQ ID NO:1 as set forth in the claims. (See Written Description guidelines published in the Federal Register/Vol. 66, No. 4/Friday, January 5, 2001/Notices: p. 1099-1111).

APPLICANT'S ARGUMENTS

The Applicant argues that their amendments address the rejections (see third paragraph on page 11 of the response). This is not persuasive, however, because the amendments continue to encompass numerous "derivatives" of SEQ ID NO:1, and they continue to encompass transformants and transgenic plants other than Arabidopsis.

The Applicant argues that they have taught 16 variants of SEQ ID NO:1 and the relationship to 18S rDNA from various different plants (see paragraph bridging pages 11-12 of the response). They also argue that they have listed different plants

in the specification (see second paragraph on page 12 of the response). This is not persuasive, however, because the instant claims require that the polynucleotide function as an IRES in a plant (see claim 1), however, none of these variants have been demonstrated to have IRES activity, and SEQ ID NO:1 has not been shown to function in any plant other than Arabidopsis.

14. Claims 1, 4, 5-9, and 11 remain and new claim 13 is rejected under 35 U.S.C. 112, first paragraph, for lack of scope of enablement for the reasons of record stated in the previous Office Action mailed on July 1, 2008, and for the reasons stated below, because the specification, while being enabling for a polynucleotide comprising 10 repeats of SEQ ID NO:1 that functions as an IRES in Arabidopsis, and a vector comprising said polynucleotide and a transformed Arabidopsis plant comprising said polynucleotide, does not reasonably provide enablement for a polynucleotide comprising DNA of SEQ ID NO:1 or DNA "derived from" SEQ ID NO:1, or for any transformant or transgenic plant other than Arabidopsis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The Applicant's amendments to the claims necessitated modifications to the previous rejection. The Applicant's arguments in the response filed on Nov. 3, 2008, were fully considered but were not found to be persuasive.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are broadly drawn to a polynucleotide which functions as an IRES in a plant and comprises 7 – 10 repeats of DNA of SEQ ID NO:1 or 7 – 10 repeats of DNA derived from SEQ ID NO:1 by the substitution, deletion, addition, and insertion of two to five bases; and to a vector and plant comprising said polynucleotide. The claims limit the substitution, deletion, addition, and insertion to 5 bases, however, SEQ ID NO:1 is only 12 bases in length, therefore, if one were to delete 5 bases and substitute 5 bases; there would only be two of the original bases remaining in a 7-base nucleic acid. Then one can add 5 bases and insert 5 bases, and one would have a 17-base nucleic acid that has only 2 bases from SEQ ID NO:1 remaining.

The Applicants teach the nucleic acid of SEQ ID NO:1 which is 12 nucleotides in length (see sequence listing). They teach a construct comprising 10 repeats of

SEQ ID NO:1 with spacer sequences between the repeats (see paragraph 0060 on page 17), and they teach a construct comprising 10 repeats of SEQ ID NO:1 without spacer sequences (see first paragraph on page 21). The Applicants teach an IRES from ECMV that is known to function in mammal cells and tobacco (see last paragraph on page 18) and a construct comprising this ECMV IRES (see second paragraph on page 21). The ECMV IRES does not appear to be related to the instant invention of SEQ ID NO:1, and the Applicant has not compared the sequences of the ECMV IRES and the sequence of SEQ ID NO:1. They teach transgenic Arabidopsis plants transformed with these constructs (see page 19); and they teach that the effect on expression from using 10 repeats without spacers was "far increased" (see paragraph bridging pages 21-22) and the effect on expression from using 10 repeats with spacers was "slightly increased" (see second paragraph on page 22). They teach that the effect on expression from using the ECMV IRES was not increased (see third paragraph on page 22). which demonstrates that an IRES that is active in tobacco and mammalian cells is not active in Arabidopsis.

The Applicants do not teach any DNAs "derived from" SEQ ID NO:1 that function as an IRES. The Applicants do not teach that SEQ ID NO:1 has IRES activity in any plant other than Arabidopsis, and they do not teach that it has IRES activity when there are less than 10 repeats of SEQ ID NO:1 present.

For example, the state-of-the-art is such that one of skill in the art cannot predict which species of plants a nucleic acid will function as an IRES in; see

Applicant's own data demonstrating that the ECMV IRES that functions and mammalian and tobacco cells did not function in Arabidopsis (see third paragraph on page 22; and see Urwin et al ((2000) The Plant Journal; Vol. 24, pp. 583-589). As discussed above, the recitation of a DNA "derived from" SEQ ID NO:1 includes a large number of molecules, and the instant specification has not provided any guidance about what nucleotides can be substituted, deleted, or added and still retain IRES activity.

Given the lack of guidance in the instant specification, undue trial and error experimentation would be required for one of skill in the art to make an endless number of derivatives of SEQ ID NO:1, and test each one for IRES activity. One of skill in the art would be left to transform multitudes of different plant species to determine in which plants (if any other than Arabidopsis) the nucleic acid of SEQ ID NO:1 can function as an IRES and to determine how many repeats are necessary for IRES function.

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to make and use the claimed invention, and therefore, the invention is not enabled throughout the broad scope of the claims.

APPLICANT'S ARGUMENTS

The Applicant argues that their amendments address the rejections (see third paragraph on pages 13-14 of the response). This is not persuasive, however, because the amendments continue to encompass numerous “derivatives” of SEQ ID NO:1, and they continue to encompass transformants and transgenic plants other than *Arabidopsis*.

The Applicant argues that the specification has provided detailed sequence information and particular sequences (SEQ ID NOs: 5-20) (see paragraph bridging pages 14-15 of the response). This is not persuasive, however, because none of the claims are limited in scope to SEQ ID NOs: 5-20, therefore, this is arguing a limitation that is not in the claims. Furthermore, even if such a limitation were introduced, these sequences have not been shown to have IRES activity and none of the sequences have been shown to have IRES activity in any plant other than *Arabidopsis*.

The Applicant argues that they have provided guidance about how to make the mutations in the sequences (see page 15 of the response). This is not persuasive, however, because the art teaches that IRES function is highly unpredictable (see Urwin et al).

Claim Rejections - 35 USC § 102

15. Claims 1, 4-6, 8, and 9 remain rejected and new claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Alonso et al (GenBank Accession BH789726 (2002), pp. 1-2) for the reasons of record stated in the previous Office Action mailed on July 1, 2008, and for the reasons stated below. The Applicant's amendments to the claims necessitated modifications to the previous rejection. The Applicant's arguments in the response filed on Nov. 3, 2008, were fully considered but were not found to be persuasive.

The claims are drawn to a polynucleotide which functions as an IRES in a plant and comprises 7 – 10 repeats of DNA of SEQ ID NO:1 or 7 – 10 repeats of DNA derived from SEQ ID NO:1 by the substitution, deletion, addition, and insertion of two to five bases; and to a vector and plant comprising said polynucleotide. The claims limit the substitution, deletion, addition, and insertion to 5 bases, however, SEQ ID NO:1 is only 12 bases in length, therefore, if one were to delete 5 bases and substitute 5 bases; there would only be two of the original bases remaining in a 7-base nucleic acid. Then one can add 5 bases and insert 5 bases, and one would have a 17-base nucleic acid that has only 2 bases from SEQ ID NO:1 remaining.

Alonso et al teach a nucleic acid that comprises the complete nucleotide sequence of SEQ ID NO:1 (see alignment and see reference provided with

restriction requirement). This nucleic acid inherently has the property of IRES activity in Arabidopsis plants. The claims recite repeats of DNA (a) or (b); and the nucleic acid taught by Alonso et al comprises one polynucleotide of SEQ ID NO:1, but in addition, it comprises multiple “derivatives” of SEQ ID NO:1 that retain at least 2 bases from SEQ ID NO:1; for example there are ten “T”s and ten “A”s and these repeats of “T” and “A” are “derivative”s of SEQ ID NO:1 with deletions, substitutions, insertions, and additions. As discussed in the rejection under 35 USC 112, 2nd paragraph, it is unclear how to interpret the positions recited in the new claim 13, because it is unclear if these positions are before or after the deletions, and insertions, and additions. The sequence taught by Alonso et al comes from a TDNA insertion line (see “Definition”); and these insertion lines comprise the NPTII gene as a selectable marker that comprises a promoter that functions in plants. These TDNA insertion lines are transgenic plants that have a polynucleotide incorporated in the genome, including the nucleic acid taught by Alonso et al which comprises a sequence with 100% identity to SEQ ID NO: 1 and repeats of nucleic acids with “T” and “A” that are “derivatives” of SEQ ID NO:1.

APPLICANT’S ARGUMENTS

The Applicant argues that Alonso does not teach a DNA of SEQ ID NO:1 or a DNA derived from SEQ ID NO:1 by the substitution, deletion, addition, and insertion of two to five bases (see page 16 of the response). This is not persuasive, however, because the claims limit the substitution, deletion, addition, and insertion

to 5 bases, however, SEQ ID NO:1 is only 12 bases in length, therefore, if one were to delete 5 bases and substitute 5 bases; there would only be two of the original bases remaining in a 7-base nucleic acid. Then one can add 5 bases and insert 5 bases, and one would have a 17-base nucleic acid that has only 2 bases from SEQ ID NO:1 remaining. Therefore, any nucleic acid with at least 2 bases from SEQ ID NO:1 present in a polynucleotide from 7 - 17 bases in length satisfies this limitation; and such nucleic acids are taught by Alonso et al.

16. Claims 1, 4-9, and 11 remain rejected and new claim 13 is rejected under 35 U.S.C. 102(a) and 35 USC 102(e) as being anticipated by La Rosa et al (US 2004/0031072 A1; published on Feb. 12, 2005, filed as Application No. 10/424,599 on April 28, 2003, with priority to Application No. 09/304,517 which was filed on May 6, 1999), for the reasons of record stated in the previous Office Action mailed on July 1, 2008, and for the reasons stated below. The Applicant's amendments to the claims necessitated modifications to the previous rejection. The Applicant's arguments in the response filed on Nov. 3, 2008, were fully considered but were not found to be persuasive.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15. The rejection under 35 USC 102(a) will be withdrawn if the Applicant provides a translation of the foreign

priority document JP 2004-008025 and if the foreign priority document provides adequate support for the claimed invention. The rejection under 35 USC 102(e) cannot be overcome by providing a translation of the foreign priority document.

The claims are drawn to a polynucleotide which functions as an IRES in a plant and comprises 7 – 10 repeats of DNA of SEQ ID NO:1 or 7 – 10 repeats of DNA derived from SEQ ID NO:1 by the substitution, deletion, addition, and insertion of two to five bases; and to a vector and plant comprising said polynucleotide. The claims limit the substitution, deletion, addition, and insertion to 5 bases, however, SEQ ID NO:1 is only 12 bases in length, therefore, if one were to delete 5 bases and substitute 5 bases; there would only be two of the original bases remaining in a 7-base nucleic acid. Then one can add 5 bases and insert 5 bases, and one would have a 17-base nucleic acid that has only 2 bases from SEQ ID NO:1 remaining.

La Rosa et al teach a nucleic acid comprising a polynucleotide with 100% identity to the instant SEQ ID NO:1 (see alignment). They refer to this nucleic acid as SEQ ID NO:122,992. This nucleic acid inherently has the property of IRES activity in Arabidopsis plants. The claims recite repeats of DNA (a) or (b); and the nucleic acid taught by La Rosa et al comprises one polynucleotide of SEQ ID NO:1, but in addition, it comprises multiple “derivatives” of SEQ ID NO:1 that retain at least 2 bases from SEQ ID NO:1; for example there are ten “T”s and ten “A”s and these repeats of “T” and “A” are “derivative”s of SEQ ID NO:1 with deletions,

substitutions, insertions, and additions. As discussed in the rejection under 35 USC 112, 2nd paragraph, it is unclear how to interpret the positions recited in the new claim 13, because it is unclear if these positions are before or after the deletions, and insertions, and additions. LaRosa et al claim a recombinant DNA construct comprising this polynucleotide (see claim 1); and they teach a method of producing a plant having an improved property, by transforming a plant with a construct comprising the polynucleotide and a promoter (see claim 3). They teach vectors comprising this polynucleotide (see page 7, paragraph 0068), and they teach transformation of plants with these vectors (see page 8).

APPLICANT'S ARGUMENTS

The Applicant argues that LaRosa does not teach a DNA of SEQ ID NO:1 or a DNA derived from SEQ ID NO:1 by the substitution, deletion, addition, and insertion of two to five bases (see page 16 of the response). This is not persuasive, however, because the claims limit the substitution, deletion, addition, and insertion to 5 bases, however, SEQ ID NO:1 is only 12 bases in length, therefore, if one were to delete 5 bases and substitute 5 bases; there would only be two of the original bases remaining in a 7-base nucleic acid. Then one can add 5 bases and insert 5 bases, and one would have a 17-base nucleic acid that has only 2 bases from SEQ ID NO:1 remaining. Therefore, any nucleic acid with at least 2 bases from SEQ ID NO:1 present in a polynucleotide from 7 - 17 bases in length satisfies this limitation; and such nucleic acids are taught by LaRosa et al.

17. Claims 1, 4-8, and 11 remain rejected and new claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Akbergenov et al (Nucleic Acids Research (2004) Vol. 32, pp. 239-247; published online Jan. 12, 2004) for the reasons stated below. After reviewing the previous Office Action, the Examiner realizes that this rejection was not written properly in the previous Office Action, and therefore, the Examiner is correcting that in the present Office Action and making it non-final. The Applicant's arguments in the response filed on Nov. 3, 2008, were fully considered but were not found to be persuasive.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15. The rejection under 35 USC 102(b) will be withdrawn and replaced with a rejection under 35 USC 102(a) if the Applicant provides a translation of the foreign priority document JP 2004-008025 and if the foreign priority document provides adequate support for the claimed invention.

The claims are drawn to a polynucleotide which functions as an IRES in a plant and comprises 7 – 10 repeats of DNA of SEQ ID NO:1 or 7 – 10 repeats of DNA derived from SEQ ID NO:1 by the substitution, deletion, addition, and insertion of two to five bases; and to a vector and plant comprising said polynucleotide. The claims limit the substitution, deletion, addition, and insertion to 5 bases, however, SEQ ID NO:1 is only 12 bases in length, therefore, if one were

to delete 5 bases and substitute 5 bases; there would only be two of the original bases remaining in a 7-base nucleic acid. Then one can add 5 bases and insert 5 bases, and one would have a 17-base nucleic acid that has only 2 bases from SEQ ID NO:1 remaining.

Akbergenov et al teach nucleic acids that are “derivatives” of SEQ ID NO:1 (See Figure 1 on page 241). They teach that this nucleic acid has the property of enhancing translation by binding the ribosome (which is IRES activity). The claims recite repeats of DNA (a) or (b); and the nucleic acid taught by Akbergenov et al comprises multiple “derivatives” of SEQ ID NO:1 that retain at least 2 bases from SEQ ID NO:1; for example there are ten “T”s and ten “A”s and these repeats of “T” and “A” are “derivative”s of SEQ ID NO:1 with deletions, substitutions, insertions, and additions. As discussed in the rejection under 35 USC 112, 2nd paragraph, it is unclear how to interpret the positions recited in the new claim 13, because it is unclear if these positions are before or after the deletions, and insertions, and additions. Akbergenov et al teach vectors that comprise these nucleic acids in addition to the 35 S promoter and nucleic acids encoding CAT and GUS reporter proteins (see page 244). They teach the introduction of these plasmids into *O. violaceus* protoplasts and protoplasts from *Nicotiana plumbaginifolia* leaves (see page 244).

APPLICANT'S ARGUMENTS

The Applicant argues that Akbergenov does not teach a DNA of SEQ ID NO:1 or a DNA derived from SEQ ID NO:1 by the substitution, deletion, addition, and insertion of two to five bases (see page 16 of the response). This is not persuasive, however, because the claims limit the substitution, deletion, addition, and insertion to 5 bases, however, SEQ ID NO:1 is only 12 bases in length, therefore, if one were to delete 5 bases and substitute 5 bases; there would only be two of the original bases remaining in a 7-base nucleic acid. Then one can add 5 bases and insert 5 bases, and one would have a 17-base nucleic acid that has only 2 bases from SEQ ID NO:1 remaining. Therefore, any nucleic acid with at least 2 bases from SEQ ID NO:1 present in a polynucleotide from 7 - 17 bases in length satisfies this limitation; and such nucleic acids are taught by Akbergenov et al.

18. No claim is allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHY K. WORLEY whose telephone number is (571)272-8784. The examiner is on a variable schedule but can normally be reached on M-F 10:00 - 4:00, with additional variable hours before 10:00 and after 4:00 with additional variable hours before 10:00 and after 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Cathy K. Worley/
Patent Examiner, Art Unit 1638